94063d

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX 303-236-3100

December 3, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael B. Engberg, Managing Partner
Herbal Remedies USA, LLC
130 West 2nd Street
Casper, Wyoming 82601

Ref #: DEN-03-08

Dear Mr. Engberg:

This letter is in reference to your firm's marketing and distribution of colloidal silver products as dietary supplements. Examples of such products that you market include: TriMedica Enhanced Colloidal Silver Liquid (listed on your website as "Colloidal Silver Liquid"), and First Defense ChildLife Formula.

Our review of your website (www.herbalremedies.com) reveals that you are promoting your colloidal silver products for the prevention or treatment of numerous diseases and conditions, including Escherichia coli, Candida albicans, tooth decay, blood poisoning, cancer, colitis, dysentery , gastritis, gonorrhea, herpes, hepatitis, infantile diseases, keratitis, leprosy, lesions, Lyme disease, malaria, pleurisy , pneumonia, scarlet fever, septicemia, Staph infections, Strep infections, "stomach flu," toxemia, ulcers, tonsillitis, tuberculosis, whooping cough, and yeast infections. Your website also claims that colloidal silver is "effective against more than 650 disease causing organisms" and promotes it as a "natural antibiotic" and "The Natural Alternative to Antibiotics."

In addition, your webpage for First Defense ChildLife Formula states the product is a "... natural broad spectrum anti-infective formula" with "anti-bacterial" and "anti-viral" properties. Your webpage recommends First Defense ChildLife Formula for "cold, cough, flu, fever, sinusitis, sore throat or ear infection." The descriptions of the ingredients of First Defense ChildLife Formula also contain numerous disease treatment and prevention claims. **Colloidal Silver:** "effective against more than 650 different

PURGED

infective organisms including bacteria, viruses, fungi and parasites.... stimulate phagocytosis, the process whereby immune cells directly attack, ingest and remove pathogens from both the blood and lymphatic fluids." **Olive Leaf Extract:** "directly inactivating viruses.... directly penetrate infected cell hosts and inhibit viral replication." **St. John's Wort:** "potent anti-bacterial and anti-viral agent.... improving recovery time from all types of bacterial and viral infections." **Zinc gluconate:** "reducing the severity of cold symptoms... dramatically improving recovery time for both mild and severe infections."

The booklet entitled "Colloidal Silver The Amazing Natural Alternative to Antibiotics" by Martha M. Christy (the Christy booklet) was shipped accompanying colloidal silver products sold by you. Therefore, the Christy booklet is labeling as defined in Section 201(m) of the Act. This booklet promotes colloidal silver products for numerous diseases and conditions, including but not limited to: dysentery, diarrhea, colitis, tonsillitis, angina, septic ulcers, gonorrhea, enlarged prostate, septicemia (blood poisoning), whooping cough, influenza, Staphylococcus aureus, Escherichia coli, Anthrax, Epstein-Barr Syndrome, hepatitis, and malaria.

Your colloidal silver products are misbranded under sections 403 (a)(1) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they bear labeling that is false and misleading because the claims made for the products on your website and in the Christy booklet are not supported by reliable scientific evidence. The Act prohibits the marketing of misbranded foods (including dietary supplements) and drugs in interstate commerce. Even if they meet the definition of a dietary supplement, your colloidal silver products are also drugs as defined in section 201(g)(1)(B) of the Act because they are intended to treat or prevent diseases. Further, they are new drugs within the meaning of section 201(p) of the Act because they are not generally recognized as safe and effective for the uses suggested in their labeling. As new drugs, the products may not be introduced or delivered for introduction into interstate commerce pursuant to section 505(a) of the Act, because no approval of a new drug application (NDA) filed pursuant to section 505(b) of the Act is in effect, nor an exception pursuant to section 505(i) of the Act.

This letter is not intended to be an all-inclusive review of your firm's labeling and products. Our review shows objectionable claims for other products you market, including claims to prevent or treat serious diseases such as cancer, hepatitis, fibromyalgia, hypercholesterolemia (high cholesterol), and herpes. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the attention of Shelly Maifarth, Compliance Officer, Food and Drug Administration at the attached letterhead address.

Sincerely,

B. Belinda Collins
District Director

cc: Mr. Tom Wharton, Managing Partner
Herbal Remedies USA LLC
5922 So 166th St.
Omaha, Nebraska 68135